

NOSB Materials Committee
Presented by Rose Koenig, Chairperson
Recommendation for Revision of FR Petition Notification
Draft 1 – for discussion

Introduction

In July 2000, the USDA National Organic Program (NOP) published a Federal Register Notice proposed rule entitled “Information to be Included in a Petition.” The FR notice currently functions as instructions to petitioners and as guidance to TAP contractors. The FR notice was posted as a proposed rule, and was never posted as a final rule. Further, it was posted prior to the NOP Final Rule, and does not take into account all applicable sections of the Final Rule.

The NOSB Materials Committee (MC) has been asked by the NOP to review the FR Notice in order to modify it to improve the materials review process. This working draft is presented to begin the discussion to revise and finalize the petition notice posting.

Background and Discussion

The NOSB and NOP need to modify the petition notification, instructions to petitioners, and the petition process. This will improve the ability of the technical advisory panel (TAP) contractor to evaluate and provide consistent information on each petitioned substance. It will also assist the TAP analysis of whether or not a substance is synthetic or non-synthetic (natural), based on NOP definitions and NOSB clarification of the definitions. In addition, the information provided in the petition needs to clearly address all applicable OFPA criteria.

In October 2003 the NOSB received input from two TAP contractors concerning suggested improvements to the material review process. The Organic Materials Review Institute submitted specific comments on the petition process. (Addendum B)

The concept and purpose of the National List was set forth in OFPA Sections 7USC 6517 and 6518, as discussed in the Senate report. According to OFPA, the National List is to contain “an itemization, by specific use or application, of each synthetic substance permitted or each natural substance prohibited” in organic farming and handling operations. OFPA set Guidelines for Prohibitions or Exemptions by establishing criteria that need to be considered when determining whether a substance should be added to the National List. OFPA also places boundaries around which types of substances can be considered for inclusion by specifying particular general categories that can appear on the list.

As indicated above, the July 2000 Federal Register notice currently functions as instructions to petitioners and as guidance to TAP contractors. In effect, the FR notice describes the petition procedures followed by the NOP and NOSB.

Analysis and Recommendations

The information below contains direct excerpts from the FR notice in regular text (non-bold) and recommendations and comments in **bold** text. The discussion focuses only on the section of the FR notice entitled “What Information Has to be Included in the Petition?” Other sections of the FR notice need to be revised and updated, and suggestions are provided in the Addendum A.

What Information Has to be Included in the Petition?

A petition seeking evaluation of a substance must indicate within which of the following categories the substance is being petitioned for inclusion on or removal from the National List:

- (1) Synthetic substance's allowed for use in organic crop production;
- (2) Nonsynthetic substances prohibited for use in organic crop production;
- (3) Synthetic substances allowed for use in organic livestock production;
- (4) Nonsynthetic substances prohibited for use in organic livestock production; and
- (5) Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

Recommendation 1. Add: “(6) Nonorganically produced agricultural products allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

Comment: This change brings the FR notice in line with the Final Rule, and is contingent on section 205.606 remaining as part of the National List.

R2. Add: “A person may also submit a petition to add, remove, or change an annotation to a substance currently on the National List.”

Comment: Petitioners should be informed that they may petition to add, remove, or change an annotation to a substance currently on the National List.

The petition must also include, as applicable, the following information:

1. The substance`s common name. **No change proposed.**

2. The manufacturer`s name, address and telephone number.

R3. Change “manufacturer’s” to “petitioner’s”

Comment: The current wording is misleading. Since generic substances, rather than brand name formulations, are petitioned, the NOSB needs the name, address, and telephone number of the petitioner. Otherwise, the petitioner would need to provide a list of all manufacturers of the substance, and describe all methods of manufacture. This information is more appropriately researched and provided by the TAP contractor.

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant.

R4. Change to read: “The intended or current use of the substance, according to categories in OFPA 6517(c)(1)(B) or NOP 205.601-606), as applicable. Include an explanation of how it is utilized in an organic system.
”

Comment: This section needs to be modified to list or reference the categories specified in OFPA and in section 205.600(b) of the Final Rule. The petitioner should be asked to justify why they believe the substance fits in the category based on how it is utilized in an organic system.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described. **No change proposed.**

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.

R5: Change “its” to “all”

Comment: The material review process for a generic substance needs to cover all of the possible ways a substance is manufactured because once a substance is listed, all substances with the same CAS number are allowed unless the substance is annotated on the list to limit it to a specific manufacturing process.

6. A summary of any available previous reviews by International, State or private certification programs or other organizations of the petitioned substance.

Dossiers may be available from other international standards development programs, and should be considered.

7. Information regarding regulatory status under applicable EPA, FDA, and State statutes and regulations, including registration numbers. **point of clarification .**

8. The Chemical Abstract Service (CAS) number , **International Numbering System for food additive (INS number)**, or other product numbers of the substance and labels of products that contains the petitioned substance. **Labels for multiple manufacturers should be submitted if available.**

Comment: This section needs to emphasize that labels need to be provided of as complete a compilation as possible of brand names of products that contain the petitioned substance within the specified use category. This provides the TAP contractor with names and resources that should be contacted to obtain additional information on the manufacturing and use of the substance. Recently, TAP reviews have had a limited focus on specific manufacturers and have not been inclusive of all manufacturing processes, making the reports unclear and resulting in deferred votes by the NOSB pending additional information. This could be addressed by requesting that petitioners provide numerous examples of product labels. INS numbers are a recognized by FAO and provide a better way to identify the many synonyms used for food additives.

9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

R6. Change item (c) to read: “(c) environmental impacts from its use and the impacts of all substances used during manufacture of the substance;”

Comment: Consideration of point (c) should include the toxicological data from all of the substances involved in the manufacturing process so that the environmental impacts from the manufacturing process can be evaluated. Additionally, if in the manufacturing process residual levels of extractants or other substances are present in the substance, this information should be analyzed by the TAP contactor.

May want to consider substituting the 6518 criteria here, and the processing criteria.

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10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.

Comment: Consideration should be given to require the petitioner to provide this information on all of the substances used in manufacture of the petitioned substance.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

Comment: No change. The MC and NOP need to examine if contrasting positions are being submitted on a regular basis by petitioners. The TAP contractor should be instructed to provide balance if the petitions do not present a complete picture. [e-br-don't understand this, and think this is unwieldy.]

12. A “Petition Justification Statement” which provides justification for one of the following actions requested in the petition:

When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.

When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product.

When petitioning for the removal from the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product.

Comment: This section should be amended to address synthetic and nonsynthetic nonagricultural substances petitioned for addition to or removal from 205.605 and nonorganically produced agricultural products petitioned for addition to or removal from 205.606.

This section could also request information concerning all applicable OFPA (7USC 6517 and 6518) or NOP (205.600(b)) criteria. The specific questions that the NOSB uses in the evaluation sheets could be inserted. The MC needs to look at the evaluation sheets and reword this section to reflect the intent of each bullet by asking specific questions of the petitioner.

13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

(a) Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.

(b) "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.

(c) Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."

(d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.)

Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.

(e) Each page with CBI-deletions should be marked ``CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and ``CBI- deleted."

(f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, ``pages 7 through 10 have been CBI-deleted.")

(g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

However, the National List substance evaluations will involve a public and open process. Nonconfidential information will be available for public inspection. The NOP Program Manager may request additional information from the petitioner following receipt of the petition.

R7. Insert in the last paragraph, after, "open process.", the following: "Failure to provide complete information may limit the ability of the technical advisory panel to conduct a comprehensive analysis of the substance or prevent the National Organic Standards Board from making a recommendation to the Secretary."

Comment: It is important to remind the petitioner that CBI information could limit the ability of the technical review contractor to make a comprehensive analysis of the substance. This could result in the inability of the NOSB to make a decision on the substance.

Conclusion

The Materials Committee draft is presented as a working draft to begin the process of updating and finalizing the petition notification.

